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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Owner/Contact/Date (807.92(a)(1):

Date:	August 20, 2013
Owner/Submitter:	GE Healthcare Finland Oy. Kuortaneenkatu 2 00510 Helsinki FINLAND Phone: +358 10 39411 Fax: +358 9 1463310
Primary Contact Person:	Joel Kent Manager, Quality and Regulatory Affairs GE Healthcare Phone: 781-449-8685 Fax: 781-433-1344 E-mail: joel.kent@ge.com
Secondary Contact Person:	Janne Marvola Regulatory Affairs Leader GE Healthcare Finland Oy Kuortaneenkatu 2 00510 Helsinki Finland Phone: + 358 10 394 2172 Fax: +358-92726532 E-mail: janne.marvola@ge.com

AUG 2 8 2013

Device names (807.92(a)(2)):

Trade Name:	CARESCAPE Monitor B650
Common/Usual Name:	multi-parameter patient monitor
Classification Names:	21 CFR 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Primary Product Code:	MHX
Secondary Product Code:	BZK, BZL, BZQ, CAP, CBQ, CBR, CBS, CCK, CCL, DPS, DPZ, DQA, DQK, DRT, DSI, DSJ, DSK, DXG, DXN, FLL, GWJ, GWQ, KOI, KRB, MLD, NHO, NHP, NHQ, OLT, OLW, OMC, ORT
Predicate Device(s) (807.92(a)(3)::)	K102239 CARESCAPE Monitor B650

Device Description (807.92(a)(4))::

The CARESCAPE Monitor B650 is a multi-parameter patient monitor including both new and existing subsystems. The CARESCAPE Monitor B650 includes the monitor itself, the CARESCAPE Software Platform (also called ESP software and for this submission ESP V2 software) and the battery. The CARESCAPE Monitor B650 itself has 15 inch touch screen display and a frame for parameter measurement modules. A variety of options are available to the customer including additional displays, various input devices (keyboard, mouse, bar code reader, and corded remote control), and physiological parameter measurement modules, which are existing subsystems. The CARESCAPE Monitor B650 communicates to a variety of existing OEM medical devices. The CARESCAPE Monitor B650 interfaces to a variety of other existing patient monitoring systems via a cabled or wireless network interface. The CARESCAPE Monitor B650 includes features and subsystems that are optional or configurable.

Intended Use: (807.92(a)(5):

The CARESCAPE Monitor B650 is a multi-parameter patient monitor intended for use in multiple areas and intrahospital transport within a professional healthcare facility.
The CARESCAPE Monitor B650 is intended for use on adult, pediatric, and neonatal patients and on one patient at a time.
The CARESCAPE Monitor B650 is indicated for monitoring of:

- hemodynamic (including ECG, ST segment, arrhythmia detection, ECG diagnostic analysis and measurement, invasive pressure, non-invasive blood pressure, pulse oximetry, cardiac output (thermodilution and pulse contour), temperature, mixed venous oxygen saturation, and central venous oxygen saturation),
- Respiratory (impedance respiration, airway gases (CO2, O2, N2O and anesthetic agents), spirometry, gas exchange) and
- neurophysiological status (including electroencephalography, Entropy, Bispectral Index (BIS), and neuromuscular transmission).

The CARESCAPE Monitor B650 also provides alarms, trends, snapshots and events, and calculations and can be connected to displays, printers and recording devices.
The CARESCAPE Monitor B650 can be a stand-alone monitor or interfaced to other devices. It can also be connected to other monitors for remote viewing and to data management software devices via a network.
The CARESCAPE Monitor B650 is intended for use under the direct supervision of a licensed healthcare practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.
The CARESCAPE Monitor B650 is not intended for use during MRI.

Technology (807.92(a)(6))::

The CARESCAPE Monitor B650 is a new revision of a monitor where the CARESCAPE Software Platform (also called ESP software) is version 2 whereas the existing predicate monitor CARESCAPE Monitor B650 (K102239) has software version 1.
The fundamental technology of the CARESCAPE Monitor B650 is the same as in the predicate device.
The CARESCAPE Monitor B650 with ESP V2 software uses an improved arrhythmia and ST analysis algorithm called EK-Pro V13 in the Monitor Software. It is based on the previous algorithm version EK-Pro V12, which has been cleared as part of the predicate device CARESCAPE Monitor B650 with ESP V1 software (K102239).

The CARESCAPE Monitor B650 device is as safe and effective the predicate devices.

Determination of Substantial Equivalence (807.92(b)(1)):

Summary of Non-Clinical Tests:
The CARESCAPE Monitor B650 and its applications comply with voluntary standards as detailed below. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

The CARESCAPE Monitor B650 was designed and tested for compliance to the following standards:

1. IEC 60601-1:1988, A1:1991, A2:1995, Corr1:1995, Medical Electrical Equipment Part 1: General Requirements for Safety – Second Edition
2. IEC 60601-1-1:2000, Medical Electrical Equipment - Part 1-1: General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems – Edition 2.0
3. IEC 60601-1-2:2001 + A1:2004, Medical electrical equipment – Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests – Edition 2.1
4. IEC 60601-1-4:1996 + A1:1999 (AKA ed 1.1:2000), Medical electrical equipment - Part 1: General requirements for safety - 4 - Collateral standard: Programmable electrical medical systems, Edition 1.1
5. IEC60601-1-6:2006, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – collateral Standard: Usability – Edition 2
6. IEC 60601-1-8:2006, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical

systems, Second Edition

7. IEC 60601-2-10:1987 + A1:2001, Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Nerve and Muscle Stimulators – First Edition

8. IEC 60601-2-25:1993 + A1:1999, Medical Electrical Equipment Part 2: Particular requirements for the safety of electrocardiographs – First edition

9. IEC 60601-2-26:2002, Medical electrical equipment - Particular requirements for the safety of electroencephalographs

10. IEC 60601-2-27:2005, Medical electrical equipment Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

11. IEC 60601-2-30:1999, Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment-Second Edition

12. IEC 60601-2-34:2000, Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment-Edition 2

13. IEC 60601-2-40:1998, Medical electrical equipment - Particular requirements for the safety of electromyographs and evoked response equipment

14. IEC 60601-2-49:2001, Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment-Edition 1

15. IEC 60601-2-51:2003, Medical electrical equipment Part 2-51: Particular requirements for safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs-Edition 1

16. AAMI EC11:1991/(R)2001/(R)2007, Diagnostic Electrocardiographic Devices

17. AAMI EC13: 2002/(R)2007, Cardiac monitors, heart rate meters, and alarms,

18. AAMI EC-57:1998, A1:2003, Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms

19. AAMI SP10:2002 + A1:2003 + A2:2006, Manual, electronic, or automated sphygmomanometers

20. EN1041:2008, Information supplied by the manufacturer with medical devices

21. EN1060-1:1995 +A1:2002, Non-invasive sphygmomanometers- Part 1: General requirements

22. EN1060-3:1997 +A1:2005, Non-invasive sphygmomanometers- Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

    Except for the following clause:
    - 7.9 for PDM module: Testing performed in accordance with EN 1060-4

23. EN 12470-4:2000, A1:2009, Clinical Thermometers – Part 4: Performance of Electrical Thermometers for Continuous Measurement

    Except for the following clauses:
    - 6.3 b) Temperature measurement error with single use probes exceeded maximum permissible error.
    - 6.4: The response time of the Esophageal stethoscope with temperature probe exceeds 150s for the probe sizes 18F and 24F.

24. ISO 21647:2004 + C1:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors

25. ISO9919:2005, Medical electrical equipment Particular requirements for the safety and essential performance of pulse oximeter equipment for medical use - Second Edition

26. IEC62304:2006, Medical device software - Software life cycle processes

27. IEC62366:2007, Medical Devices – Application of usability engineering to medical devices (General)

Clinical (807.92(b)(2)):

Summary of Clinical Tests:
The subject of this premarket submission, CARESCAPE Monitor B650 did not require clinical studies to support substantial equivalence.

Conclusion (807.92(b)(3)):

GE Healthcare considers the CARESCAPE Monitor B650 to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 28, 2013

GE Healthcare Finland Oy
c/o Mr. Joel Kent
Kuortaneenkatu 2
Helsinki, FIN-00510 FI

Re: K131223
Trade/Device Name: Carescape Monitor B650
Regulation Number: 21 CFR 870.1025
Regulation Name: Multiparameter Patient Monitor (Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms))
Regulatory Class: Class II
Product Code: MHX, BZK, BZL, BZQ, CAP, CBQ, CBR, CBS, CCK, CCL, DPS, DPZ, DQA, DQK, DRT, DSI, DSJ, DSK, DXG, DXN, FLL, GWJ, GWQ, KOI, KRB, MLD, NHO, NHP, NHQ, OLT, OLW, OMC, ORT
Dated: August 2, 2013
Received: August 5, 2013

Dear Mr. Joel Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **CARESCAPE Monitor B650**

Indications for use:

The CARESCAPE Monitor B650 is a multi-parameter patient monitor intended for use in multiple areas and intrahospital transport within a professional healthcare facility.

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The CARESCAPE Monitor B650 is not intended for use during MRI.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.08.28 09:54:29 -04'00'